AUG 2 2 2001

K011817

510(k) Summary for the Bridge FX Stent Delivery System

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.
Submitter	Medtronic AVE, Inc. Peripheral Technologies 2170-A Northpoint Parkway Santa Rosa, California 95407
Contact Person	John Riolo Vice President, Regulatory Affairs and Quality Assurance Phone: (707) 541-3271 FAX: (707) 566-1159 e-mail: john.riolo@medtronic.com
Date Prepared	June 11, 2001
Trade Name	Bridge FX Stent Delivery System
Common Name	Biliary Stent and Delivery System
Classification Name	Biliary Catheter and Accessories
Device Classification	Classification: Class II Classification Panel: 78FGE Regulation Number: 21 C.F.R. §876.5010
Predicate Devices	• Bridge X3 (K000744, 6/5/00) • Bridge Flexible/Hi-Flex (K992569, 8/31/99; K993145, 10/21/99)
Performance Standards	Performance standards have not been established by the FDA under section 514 of the Federal, Food, Drug and Cosmetic Act

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510(k) Summary for the Bridge FX Stent Delivery System

Device Description	The Bridge FX Stent Delivery System consists of a balloon-expandable intralumenal, 316L stainless steel stent pre-mounted onto the balloon of an over-the-wire delivery catheter. The device is available in diameters ranging from 6-10 mm and in several lengths including 20, 30, 40, and 60 mm. The delivery system has two radiopaque marker bands to aid in the placement of the stent during fluoroscopy. The delivery system is compatible with 0.035" guidewires and has useable lengths of 80 and 130 cm. The device is provided in a sterile package.
Indications for Use	The **Medtronic AVE Bridge FX Stent Delivery System** is intended to maintain patency of a bile duct, which is occluded by a malignant tumor.
Technological Characteristics	The Medtronic AVE Bridge FX Stent Delivery System is substantially equivalent to Medtronic AVE's previously-cleared Bridge products. The devices have the same indications for use, intended use, and the same fundamental scientific technology. Difference between the subject and predicate devices are minor and are not relevant to its ability to maintain patency of a bile duct.
Nonclinical Performance	Preclinical testing was conducted to confirm the safe and effective performance of the Bridge FX. The device passed biocompatibility testing.
Sterilization	The Bridge FX is provided sterile. The device is not intended for reuse or resterilization.
Conclusion	The Medtronic AVE Bridge FX Stent Delivery System is substantially equivalent to Medtronic AVE's currently cleared and marketed Bridge products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2001

Mr. Kevin Drisko
Senior Regulatory Affairs Specialist
Medtronic AVE, Inc.
2170 A Northpoint Parkway
SANTA ROSA CA 95407

Re: K011817
Medtronic AVE Bridge™ FX Biliary Stent Delivery System
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: July 20, 2001
Received: July 23, 2001

Dear Mr. Drisko:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K011817

Device Name: Medtronic AVE Bridge™ FX Biliary Stent Delivery System

FDA's Statement of the Indications For Use for device:

The Medtronic AVE Bridge™ FX Biliary Stent Delivery System is intended to maintain patency of a bile duct, which is occluded by a malignant tumor.

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011817